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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,917	04/11/2006	Yipu Feng	13695/1	5543
26646	7590	09/29/2009	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			KWON, BRIAN YONG S	
		ART UNIT	PAPER NUMBER	
		1614		
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		09/29/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,917	<b>Applicant(s)</b> FENG ET AL.
	<b>Examiner</b> Brian-Yong S. Kwon	<b>Art Unit</b> 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on 16 June 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 6-8 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 6-8 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08e)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

***Status of Application***

1. Acknowledgement is made of applicant's amendment/remarks filed on 06/16/2009. By the amendment, claims 4-5 have been cancelled and claim 6 has been amended.
2. Applicant's amendment changing the scope of the invention by cancelling "preventing" or "prevention" and reciting "to reduce the volume of the cerebral infarction" in claim 6 necessitates a new ground of rejection in this Office Action.
3. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over. Chang et al. (*Acta Pharmacologica Sinica*, August 2003, 24(8), pp. 796-804) in view of Xiong et al (*Yaoxue Xuebao*, 2000, 35(6), pp. 408-412) or and further in view of I佐宗義 et al. (*Tokai J Exp Clin Med.*, vol. 23, No. 3, pp. 103-117, 1998).

Chang teaches use of 3-n-butylphthalide, preferably l-3-butylphthalide (NBP) as effective agent for improving ischemia-induced apoptosis, particularly transient focal cerebral ischemia-apoptosis (abstract; para. 3 of page 803), wherein said compound is administered in dosage amounts in range from 5mg-20mg/kg to a subject (Figures). Chang discloses that the beneficial effects NBP on cerebral ischemia-induced apoptosis might be useful for the treatment of ischemic cerebrovascular diseases

Xiong et al. (*Yaoxue Xuebao*, 2000, 35(6), pp. 408-412). Xiong teaches use of butylphthalide including l-3-butylphthalide (NBP) as effective agent for improving mitochondrial injury during cerebral ischemia (abstract), wherein said compound is administered in dosage amounts in range from 5mg-10mg/kg to a subject (Figures). Xiong discloses that the

improving effects of NBP on mitochondrial injury and morphological changes might contribute to its therapeutic action on experimental stroke.

Izozumi is being provided as a supplemental reference to demonstrate the state of the art knowledge in using focal cerebral ischemia model as an experimental model of cerebral infarction (page 106, column 1, para. 3 through page 108, column 1, para. 1).

The teaching of Chang differs from the claimed invention in the use of NBP in the therapeutic treatment of cerebral infarction. To incorporate such teaching into the teaching Chang, would have been obvious in view of Xiong who teaches or suggest the use of NBP for the treatment of (cerebral) stroke and Izozumi who teaches the focal cerebral ischemia animal model as a well recognized experimental model of cerebral infarction.

One having ordinary skill in the art has basis for perceiving those studies provided in Xiong or Chang as constituting recognized procedure with clear relevance to therapeutic utility in treating cerebral infarction, in animals or humans.

The prior art does not disclose the underlying pharmacological mechanism of “to reduce the volume of the cerebral infarction”. However, the fact that the applicant may have discovered a new pharmacological mechanism for L-butylphthalide of formula (I) is not considered patentably distinctive over the prior art which are directed to the same therapeutic application (for the treatment of cerebral infarct induced by focal cerebral ischemia). The examiner considers that such property seems to be a necessary consequence of what is deliberately intended in the prior art method. . Thus, the references in combination make obvious the instant invention.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 608 are properly rejected under 35 U.S.C. 103.

### Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/  
Primary Examiner, Art Unit 1614